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|---|-------------|--------------------------|-------------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 09/361,652 | 07/27/99 | ZUKER | C 2307E-088610 |
| TOWNSEND AND TOWNSEND AND CREW TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO CA 94111-3834 | | HM12/0103 | EXAMINER BRANNOCK, M |
| | | ART UNIT | PAPER NUMBER 1646 12 |
| | | DATE MAILED: 01/03/01 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | | | |
|-----------------|-------------------------|----------------|-------------------|
| Application No. | 09/361,652 | Applicant(s) | C.S. Zuker et al. |
| Examiner | Michael Brannock, Ph.D. | Group Art Unit | 1646 |



Responsive to communication(s) filed on Oct 3, 2000

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1 and 3-63 is/are pending in the application.

Of the above, claim(s) 19-33 and 36 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1, 3-18, 34, 35, and 61-63 is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1 and 3-63 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of Application: Claims and Amendments

1. Claims 1, 3-63 are pending, claims 1, 3-18, 34, 35, 61-63 are currently under examination.
2. Applicant is notified that the amendments put forth in Paper 11, 10/3/00, have been entered in full.

Response to Amendment

3. Regarding the issue raised in item 4 of Paper 8 (4/7/00) concerning priority, it is acknowledged that the instant application claims priority only to provisional application 60/094,465.

Withdrawn Objections/Rejections:

4. The rejection claims 9-18 under 35 U.S.C. 112, second paragraph, as set forth in item 7 of Paper 8 is withdrawn in view of Applicant's amendments.
5. The rejection of claims 1, 3, 6, 8, 10, 11, 12, 14-18, 34, 35 and 61-63 under 35 U.S.C. 112, first paragraph, as set forth in item 9 of Paper 8, is withdrawn in view of the subsequent finding that the claims lack a specific or otherwise substantial utility, see below.

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Maintained Objections:

6. The objection to the specification put forth in item 5 of Paper 8 is maintained until the required updates are made.
7. Claim 7 stands rejected under 35 U.S.C. 112, second paragraph, for the reason set forth in item 7a of Paper 8. Applicant argues that the term "stringent conditions", as it is used in the art of PCR is well known to be "standard conditions" and that such standard conditions are well known in the art, e.g. as those disclosed by the Innis et al. reference. This argument has been fully considered but not deemed persuasive because neither the instant specification nor the Innis reference state that only one set of conditions is standard or stringent.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1, 3-18, 34, 35 and 61-63 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. Claims 1, 3-18, 34, 35 and 61-63 are directed to polynucleotides of SEQ ID NOs 4, 5, and 6 encoding a polypeptide of SEQ ID NOs: 1, 2, and 3. The instant specification

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puts forth that the polypeptides are useful in a screening method to determine what ligands may activate or inhibit the polypeptides (see page 3) and also to determine what the physiological effects of the polypeptides might be - the effects being those on “taste cell activity”. This proposed use lacks a specific and substantial utility. It is not a specific use because any integral membrane protein expressed on taste receptor cells could be used in exactly the same way. Furthermore, the proposed use of the polypeptide to screen for ligands of the polypeptide or for biologic effects of the polypeptide is not a substantial utility. A substantial utility is a practical use which amounts to more than a starting point for further research and investigation and does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be. For example, an assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease would be a practical use of the material. However, a method of modulating an unidentified aspect of what is collectively known as taste perception with an as yet unidentified material (e.g. agonists of the disclosed polypeptides) would not constitute a substantial utility. Basic research, such as studying the properties of the claimed product or the mechanisms in which the product is involved, does not constitute a substantial utility.

The specification puts forth that the claimed nucleic acids encode “taste cell specific G-protein coupled receptors” (see page 3), and that if potential modulators of the polypeptides could be found, then those modulators could be used to “customize taste”. A stated belief that a correlation exists between the polypeptides and all of the collective phenomena that are

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encompassed by the concept of taste perception is not sufficient guidance to use the claimed polynucleotides to modulate any aspect of taste perception; it merely defines a starting point for further research and investigation and presents only an invitation to one of skill in the art to perform such further research and investigation.

The specification puts forth that the polypeptides of the instant invention are specifically expressed in taste cells and that the polynucleotides could thus be used to generate taste topographic maps, elucidate the relationships between taste cells of the tongue and taste centers in the brain, or to dissect taste induced behaviors (see page 8). These proposed uses lack a specific and substantial utility. Almost every polynucleotide and polypeptide has some tissue specific pattern of expression, and absent knowledge of any ligands to the disclosed polypeptides, any polypeptide known to be expressed specifically in taste cells could be used in exactly the same ways as those proposed by Applicant (gustducin, for example) - thus, the proposed uses lack a specific utility. Additionally, these proposed uses lack a substantial utility, because these uses are merely and invitation to perform further research into the properties of the disclosed polypeptides and polynucleotides or to try to find practical uses for them.

The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed nucleic acids.

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10. Claims 1, 3-18, 34, 35 and 61-63 are also rejected under 35 U.S.C. § 112 first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

11. Claims 1, 3, 5-18, 34, 35, and 61-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses polynucleotides of SEQ ID NO: 4, 5, and 6, yet the claims encompass polynucleotides not described in the specification, e.g., sequences from other species, mutated sequences, allelic variants, or sequences that have a recited degree of identity. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. Although one of skill in the art would reasonably predict that these sequences exist, one would not be able make useful predictions as to the nucleotide positions or identities of those sequences based on the information disclosed in the specification.

With the exception of the of the polynucleotide of SEQ ID NO: 4, 5, and 6, the skilled artisan cannot envision the detailed chemical structure of the encompassed variants. Therefore, only the polynucleotide of SEQ ID NO: 4, 5, and 6, and polynucleotides *consisting* of fragments

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thereof, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



*Michael Brannock
Primary Examiner*

December 29, 2000